EG – KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY · DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ · EC – СЕРТИФИКАТ СООТВЕТСТВИЯ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante: / Название и адрес производителя:	**Wöhlk Contactlinsen GmbH** **Bürgermeister-Schade-Str. 12 - 16** **24232 Schönkirchen** **Germany**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che / мы заявляем о полной ответственности, что

das hergestellte Medizinprodukt: /
the manufactured medical device: /
le producit de dispositif médical: /
el producto de dispositivo medico: /
то произведённый медицинский продукт:

wöhlk AS2
wöhlk AS2 RT
wöhlk AS2 BTK
wöhlk AS2 BT
wöhlk AS2 VPT

EGO_as 2
EGO_as 2 RT
EGO_as 2 BTK
EGO_as 2 BT
EGO_as 2 VPT

wöhlk BIFO AS 2
wöhlk BIFO AS 2 RT
wöhlk BIFO AS 2 BTK
wöhlk BIFO AS 2 BT
wöhlk BIFO AS 2 VPT

EGO_bifo as 2
EGO_bifo as 2 RT
EGO_bifo as 2 BTK
EGO_bifo as 2 BT
EGO_bifo as 2 VPT

wöhlk MULTI AS 2
wöhlk MULTI AS 2 RT
wöhlk MULTI AS 2 BTK
wöhlk MULTI AS 2 BT
wöhlk MULTI AS 2 VPT

EGO_multi as 2
EGO_multi as 2 RT
EGO_multi as 2 BTK
EGO_multi as 2 BT

wöhlk
CONTACTLINSEN

EGO_multi as 2 VPT

Diagnoselinse wöhlk AS 2
Diagnoselinse wöhlk AS 2 RT
Diagnoselinse wöhlk AS 2 BTK
Diagnoselinse wöhlk AS 2 BT
Diagnoselinse wöhlk AS 2 VPT

Diagnoselinse EGO_as 2
Diagnoselinse EGO_as 2 RT
Diagnoselinse EGO_as 2 BTK
Diagnoselinse EGO_as 2 BT
Diagnoselinse EGO_as 2 VPT

Diagnoselinse wöhlk BIFO AS 2
Diagnoselinse wöhlk BIFO AS 2 RT
Diagnoselinse wöhlk BIFO AS 2 BTK
Diagnoselinse wöhlk BIFO AS 2 BT
Diagnoselinse wöhlk BIFO AS 2 VPT

Diagnoselinse EGO_bifo as 2
Diagnoselinse EGO_bifo as 2 RT
Diagnoselinse EGO_bifo as 2 BTK
Diagnoselinse EGO_bifo as 2 BT
Diagnoselinse EGO_bifo as 2 VPT

Diagnoselinse wöhlk MULTI AS 2
Diagnoselinse wöhlk MULTI AS 2 RT
Diagnoselinse wöhlk MULTI AS 2 BTK
Diagnoselinse wöhlk MULTI AS 2 BT
Diagnoselinse wöhlk MULTI AS 2 VPT

Diagnoselinse EGO_multi as 2
Diagnoselinse EGO_multi as 2 RT
Diagnoselinse EGO_multi as 2 BTK
Diagnoselinse EGO_multi as 2 BT
Diagnoselinse EGO_multi as 2 VPT

der Klasse: / of class: /
de la classe: / di classe: / класса: **II a**

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE / по дополнению IX Закона 93/42/EEC

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll".

/meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.
/remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit.
/soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto. / соответствует требованиям законодательства медицинской продукции 93/42/EWG и их применении. заявление действительно в соответствии с принадлежащим к продукту Контрольному протоколу.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità: процедура оценки соответствия:	**Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4** **Directive 93/42/EEC Annex II, excluding Section 4** **Directive 93/42/CEE Annexe II, hors section 4** **Direttiva 93/42/CEE senza Allegato II, sezione 4** **руководство 93/42/EWG Приложение 2, без подразделения 4**
Zertifikat-Registrier-Nr.:/Certificate-Registration no:/ Certificat n°d’enregistrement:/Certificado Numero di registrazione:/Сертификáт Регистрациóнный номéр:	**HD 1566826-1**
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:/ Регистрационный орган:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Germany** **CE 0197**

Schönkirchen,2025/03/20
Ort, Datum / Place, date / Lieu, date / Luogo, data / Место, дата

Hiroko Aikawa / Managing Director